CHAPTER 2

LITERATURE REVIEWS

1. Drug management system

1.1 Concepts of Drug Management System (WHO, 2006)

Management is the act or art of being responsible or in charge and conducting or supervising something (e.g. a health center pharmacy, business, public undertaking) with a degree of skill and address. It is the judicious use of means to accomplish an end (i.e. public health). Management can also refer to the collective body of those who are responsible for an entity (e.g. a health center) or who exercise executive, administrative supervisory and regulatory control (e.g. board of governors, village health committee).

Three reasons can be given to explain why drugs need to be managed properly. Firstly, drugs are part of the link between the patient and health services. Consequently, their availability or absence will contribute to the positive or negative impact on health. Secondly, poor drug management, particularly in the public sector of developing countries, is a critical issue, but major improvements are possible that can save money and improve access. Finally, drugs are no longer the responsibility of health workers only. Political, economic, financial and traditional considerations have become so crucial in health care that it has become imperative to look at drugs and health care from these perspectives.

All of these factors contribute to appropriate financial expenditure, avoid wastage, increase access and ensure that drugs are properly used. Proper drug management may also be a source of revenue, which can be used to cater for other health care needs and in particular for disadvantaged populations.

Drug management functions are undertaken in four principal phases, which are interlinked and are reinforced by appropriate management support systems (i.e. tools). The following diagram (Figure 2.1) illustrates the drug management cycle. From drug selection to drug use, passing through procurement, storage and

distribution, a whole range of management capacities are required and necessitate using the appropriate tools within a given legal and policy framework.

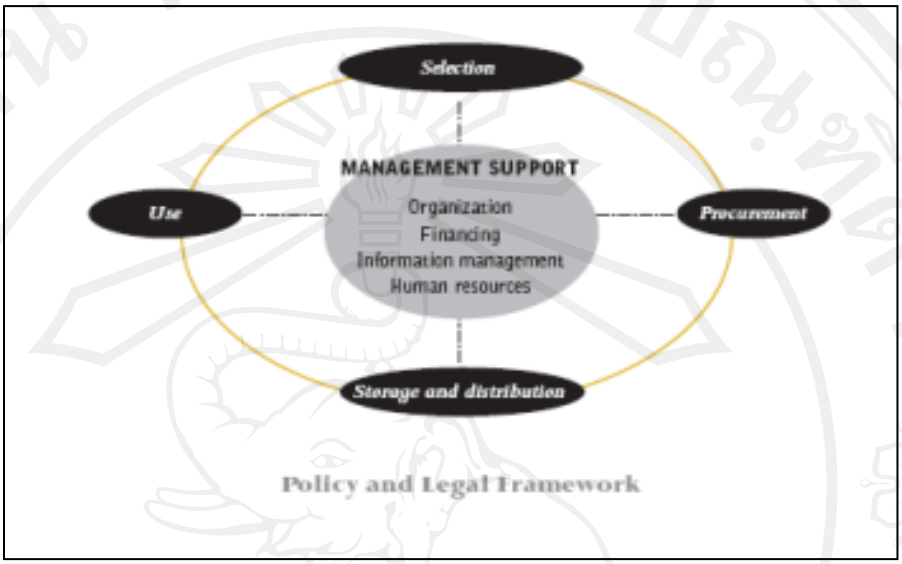

Figure 2.1: Drug Management Cycle (WHO, 2004a)

The selection of drugs for use at health centers is usually determined at the national level by the Ministry of Health and is based on a number of factors. After determination of the quantities required, based on price, delivery conditions and quality, the selected drugs go through a procurement process. After storage and distribution, the use of the drugs requires prescribing, packaging, dispensing and counseling. These tasks require qualified health workers or other relevant personnel with appropriate skills and attitudes. Management support tools are important for the acquisition of relevant skills in drug management (WHO, 1997).

1.2 Concepts of Thailand's National Drug Policy 2011

National Drug Policy (NDP) means to assure standard quality of local productivity, availability, accessibility (or effective distribution) and rational utilization of quality drugs, in terms of therapeutic efficacy and safety, of drugs. The policy can only be achieved through collaboration among government and private sectors upon synchronizing the prevailing technology and socio-economic situations, leading toward self- reliance and security of the nation. The goal of NDP is that Thai

people could access to essential drugs, rational use of drugs, and self – reliance on drugs (National Drug Committee, 2011). Strategy plan of National Drug System Development includes 4 strategies.

Strategy 1: Accessibility of drugs

Objective: to help people be able to access the essential drugs with equity, fairness, and contemporary situation. The appropriate prices should be suited for people affordability and the country economic.

Sub-strategy 1: to co-ordinate networks for accessibility of drugs.

Sub-strategy 2: to encourage patient to access the drugs and participate in health promotion.

Sub-strategy 3: to promote price of drugs in the country according to the living allowance.

Sub-strategy 4: to use benefits and/or reduce the obstacle of legal requirement for people to access the drugs.

Strategy 2: Rational use of drugs

Objective: to promote reasonable, accurately, and worthy drug use by physicians, health personnels, and people.

Sub-strategy 1: to develop monitoring system for rational use of drugs.

Sub-strategy 2: to develop production system and health manpower.

Sub-strategy 3: to develop mechanism and tool for rational use of drugs.

Sub-strategy 4: to strengthen the ability of people in rational use of drugs.

Sub-strategy 5: to promote production and quality assurance of generic drugs.

Sub-strategy 6: to develop prevention and solving system for the problems of antibiotic drug use and disease resistance.

Sub-strategy 7: to promote ethic of prescribers and terminate the sale promotion of drugs without ethical concerns.

Strategy 3: Development of pharmaceutical industries, biomaterials, and herbals for self –reliance on drugs.

Objective: to develop competency of the pharmaceutical industries, biomaterials, and herbals in country for self-reliance on drugs with stable and sustainable situation.

Sub-strategy 1: to develop and improve laws, regulations for the investment and development of the pharmaceutical industries in the country.

Sub-strategy 2: to promote research and develop pharmaceutical industries and to develop the pharmaceutical innovations to step up to the commercial level.

Sub-strategy 3: to generate resources for promotion of the production and marketing of the pharmaceutical industry in the country.

Sub-strategy 4: to create the confidence and quality assurance of drugs manufactured in the country for prescribers and people.

Strategy 4: Development of drug control system for quality assurance, effectiveness, and safety of drugs.

Objective: to assure the quality, effectiveness, and safety of drugs by competency development and promotion of the strength of drug control system in the country.

Sub-strategy 1: to develop competency of drug control system for its' efficiency and transparency following the good governance.

Sub-strategy 2: to develop surveillance system for post marketing drugs and to create drug surveillance procedure and drug alert system.

Sub-strategy 3: to review the registered drugs which highly affected the consumers and social.

1.3 Concepts of Thailand's National List of Essential Drugs 2008

Thailand followed the 31st World Health Organization Assembly recommendations on drug system management, which urged the member countries to develop their own national drug policy. For the last two decades, Thailand's NDP articulated a framework to enable sustained improvement in the Thai drug system. Economic depression and interference from politicians on drug procurement led the MOPH to improve its pharmaceutical administrative system. Initiatives to improve

efficiency in the drug system have focused on the drug list and procurement procedures.

The first and the most important component of the NDP was the National List of Essential Drugs (NLED) implemented since 1982. It was developed for community hospitals in the selection of essential drugs to be used for medical services in order to save costs and promote rational drug use. The implementation of the list is limited only to the public sector. However, the current requirements regarding the use of NLED are outlined in the Office of Prime Minister's Rules on Government Procurement which mandates public health facilities to buy drugs listed in the NLED not less than 60 percent of their drug budget (80 percent for facilities under the Ministry of Public Health), and the prices of the drugs purchased must not exceed the specified medium price.

The NLED is a measure to limit the hospitals use of relatively expensive drugs without a good reason. However, hospitals having higher number of specialists, providing more complicated care, and/or responsible for teaching medical students, usually complain and request to list more drugs than those appeared in the list. Consequently, many hospitals request to use their self-earned budget for drugs that are not in NLED. The first NLED consisted of approximately 400 drug items presented in generic name. Subsequent revisions of the list have made changes to the types and the number of drugs included in the list. The latest NLED was published and implemented in 1999. It contains two main categories including a drug list for hospitals and a drug list for primary health care. The classification of drugs for hospitals into five sub-lists (a, b, c, d, and e) is a feature which did not exist in previous lists. Hospitals at every level can use drugs in sub-list (a). Drugs in sub-list (b) are limited to some conditions. They can be purchased when a physician feels that they are better than drugs in sub- list (a) or when the hospital cannot procure drugs in sub-list (a). Drugs in sub-list (c) are drugs that are expensive and may result in serious adverse effects when they are inappropriately used. They are to be used only with prior authorization. Hospitals were required to conduct drug utilization evaluation (DUE) for drugs in sub-list (d). Drugs in sub-list (e) are allowed only in some special health care programs and their use requires prior authorization by the NLED subcommittee.

At the beginning, the NLED was used as a tool to guide drug procurement in the public sector. In 1998, it was firstly employed as a payment tool when the cabinet decided to curb drug costs along with other expenses in an attempt to contain overall expenditures of the Civil Service Medical Benefit Scheme (CSMBS). Because a large number of drugs are added to the 1999 NLED, the list is no longer maintains its original objectives to include only a limited number of "essential" drugs to serve public health purposes. The foundation of a restricted number of essential drugs in the drug list is a cost containment-based formulary decision, in contrast to a cost-outcome-based formulary decision favoring a wider range of drugs. To demonstrate that adding or rejecting a new and relatively expensive drug is clinically and economically sound, some kinds of objective assessment pharmaceutical expenditure was performed by using pharmaceutical management tools.

1.4 The policy of National Health Security Office 2010

The National Health Security Act in 2002 is the legal basis for the Universal Coverage System (UCS). The Act stipulates the establishment of the National Health Security Office (NHSO) and the National Health Security Fund. Actually, this act stipulates that every Thai citizen has entitlement to medical care under a public health protection scheme. However, Thai citizens who already have entitlement to use any existing social health protection scheme have to use those schemes.

Thailand had used the user fees model since 1945. This financial model has a potential to raise revenue into health care system. This model is not a mean to universal coverage. However, if there is limitation of government budget, the first priority should be expansion of the coverage of health care infrastructure to provide public health and prevention services. Regarding curative services, user fee model with appropriate measures to decrease financial catastrophic could be used.

Community financing is another way to raise fund for health system in addition to government budget. It can also serve other social objectives especially in community level. The Ministry of Public Health used this model for the Health Care System (HCS) phase I to III during 1983-1992, then the financial model was changed to the voluntary health insurance. Since this financial model is also not a mean to universal coverage from its limited risk pooling and its voluntary basis, financial

management skill was another problem for community financing. As a matter of fact, there are many community funds alive in Thailand and they provide series of medical and welfare benefits for their members. However, benefit in cash and in kind which they provided are only small amount of money. Therefore this financial model can be considered as a supplementary measure for moving toward universal coverage.

Drug management is a main point to control and decrease drug expenditures. Therefore, the NHSO stipulated aims to access to quality, efficacy and safety of medicines, and rational use of medicines. NHSO strategy of drug management composed of; firstly, develop procurement policies for monitoring drug access, organize the drug distribution and medical supplies necessary for the person having the right to universal health insurance system. Secondly, develop drug information systems to facilitate the utilization of development and monitoring of rational drug use. Thirdly, support quality assurance of drug use in Universal Coverage (UC). Fourthly, create the participation of other sectors in the role and participation in drug management system. And finally, enhance efficiency and fairness in procurement and compensation for medicine in security. These strategies benefit for Thai people in the health insurance system and efficiency of drug management system in the hospitals.

1.5 The Guideline of Drug Management System under MOPH 1999

MOPH stipulated the principles of drug management system reform as follows.

1.5.1 Holding the relevant purchasing regulations. They are the regulations of the Office of the Prime Minister on the supply, the regulation of the MOPH on drug and medical supply procurement and related policy to drug management of the MOPH.

1.5.2 Planning by the personnel who involve with drug use for co–operation in drug management. Committee is formed at all levels.

1.5.3 Decision making of medical supply purchasing must based on correct information of the quantities and prices.

1.5.4 Development of information system on the reference price which can be used as the base price to make a decision in purchasing, monitoring and accountability.

1.5.5 Hospital drug list is the most effective list. This list has minimum drug items as necessary and information on efficiency, quality, safety, and price of drugs is used for a decision making of drug selection.

1.5.6 Efficient drug procurement system increased the power of bargaining for the group purchasing process at provincial level. The regulation on appropriately drug quality selection and increasion of drug procurement efficiency will be able to stipulate.

1.5.7 Efficient drug inventory management system will prompt a better drug turnover and decrease drug inventory for cost reduction of reserved drugs.

1.5.8 Drug prescribing is appropriate and rationale. Feedback system of drug information to physicians is performed. Monitoring and evaluation system of drug use includes Therapeutic Drug Monitoring, Drug Use Evaluation, and feedback is also performed.

1.5.9 A reporting system of monitoring and evaluation from regional and central sectors is periodically performed together with the inspection from the outside agencies such as the Office of the Auditor General of Thailand.

2. DSM situation in Thailand

Problems, solving strategies, technologies, information, and business in connection with the Thai drug system have experienced on a rapid change during the past decade. Attempts to gather and review all relevant information to identify problems, propose direction and strategies to develop the drug system, are realized highly essential. To facilitate the development of NDP, promotion of rational drug use and domestic drug manufacturing, country self-reliance on drug supply, promotion and development of traditional and herbal drugs as well as expansion oversea's market are undertaken. All these issues are involved with DSM (Kornkasem et al., 1994). The organization infrastructure of Thai's DSM can be divided into three levels.

2.1 National level (Kornkasem et al., 1994; Orsiri, 2004; Tantivess, 2007)

Many organizations stipulate policies, regulations, measures, and guidelines which relevant the DSM following key issues to operate the DSM in country as follows.

2.1.1 Drug selection system

It is clear from the beginning that the responsibility to ensure safety and efficacy of drugs are primary vested upon drug manufacturers or importers. In addition, all drugs used in the country are obliged to meet criteria and standards established by Thai FDA for quality, safety, and efficacy. Following the NDP, the NLEM was developed, comprising essential drugs which are cost-effective and widely used to resolve major health problems. This list is enforced to be used by government hospitals. However, drugstores and consumers as well as health professionals as a whole still play important roles in drug selection. Importance issues are taken into consideration:

(1) Available of drugs in country

Drug products have been registered for use in Thailand. They can be categorized into three major groups as follows: (1) drugs according to Drug Act comprising modern drugs for human use, modern drugs for veterinary use, and traditional drugs, (2) psychotropic substances and (3) narcotics. In addition, there are additional items of drugs produced by GPO and public health institutions whereby registration requirements are exempted.

Factors influencing the number of drug formularies in the country

- Patent Act
- A large number of drug manufacturers/importers
- Lifelong valid of drug registration with low registration fee and without charge for maintenance of legislation certificate
- Availability of inappropriate drugs
- Registration of similar drug or drug with same strength

(2) Drug registration

In principle, drug registration must take into account the balance between safety and efficacy. In case of new drugs including new chemical entities, new indications, new combinations, or new delivery system, if approval is to be made,

there is a requirement for 2 years safety monitoring clearance prior to an unconditional approval. During the period of 2 year SMP (safety monitoring program) or until obtaining an unconditional approval, these new drugs can be marketed only to health facilities manned by physicians. For generic products will be allowed to register with requirement for bioequivalence study.

Formerly, drug registration procedure was not well developed, leading to the aforementioned problems of appropriate drug items. To resolve these problems, there is a need for efficient drug re-evaluation program.

(3) National List of Essential Medicine (NLEM)

As previously reiterated, the NLEM was formulated to solve the problems of increasing expenditure on drug consumption, limitation of health budget, inappropriate prescription and irrational drug use.

Drug procurement criteria of using NLEM is also established for public hospitals. For the community hospitals under MOPH, 80% of the budget for drug procurement must be used to purchase EDs. Thus, the NLEM expected to achieve rational use of drugs and strengthening other relevant activities i.e., procurement of drugs, production and importation of drugs. The development of NLEM is indeed the core of the whole drug system development.

Problems concerning the application of NLEM:

- NLEM is not updated.
- Lack of cost-effectiveness data for NLEM development.
- Breach of procurement regulation.

(4) Drug selection for health service institutions

Pharmacy and Therapeutic Committees (PTCs) appointed to undertake the task for DSM in the public hospitals. PTCs are vested interest on drug purchasing, lack of strict monitoring and control system, etc. Meanwhile, private hospitals prefer to use original drugs rather than generic drugs. So, drug selection or prescription at drugstores is generally based on local problems and decision of consumers.

2.1.2 Drug consumption

(1) Drug consumption of Thai people

Drug consumption at wholesale price amounted to 103,517.13 million bath. Drug consumption at retail price amounted to 186,330.83 million bath. Total health expenditure for Thai is 588,330.83 million baht. Therefore, it is estimated that the capita expenditure on drugs for Thai people is 9,304 baht. The percentage of drug expenditure by total health expenditure is 46.39. (Wibulpolprasert, 2010). The data indicated that Thai people to be overconsumption on drugs.

(2) Rational use of drugs

Approximately two-third of Thai people decided to purchase drugs from health professionals i.e. physicians, pharmacists, other health personnel. Critical problems concerning irrational use of drugs are evidenced as that drugs classified as dangerous, specially controlled group, psychotropics, and steroid containing traditional medicine are illegally sold in some village groceries or Village Drug Fund.

(3) Factors involving irrational use and overconsumption of drugs

- Drug information

Inacculate, imbalance, and misleading information are among key factors influencing overconsumption of drugs. In addition, educational activities for health professionals and the general public on rational use of drugs are extremely inadequate with very limited resource support and uncovered health facilities.

- Drug procurement procedure

There are various hidden benefits under drug procurement in public hospitals. The PTC approach is efficiently carried out only in some hospitals. Irrational drugs purchasing lead to irrational use of drugs. The culture of the Thai health service system creates incentive to over prescribed and dispensed drugs.

- Drug prescription within the health service system

The medical service for patients is charged by physician through the prescribed drugs. In public hospitals, drug selling is a major source of income. The culture of selling of drugs of pharmaceutical companies in Thailand is to give incentive to involving personnel for over prescribing and dispensing drugs.

2.1.3 Drug industry

Approximately two-third of drugs in Thailand is manufactured in the country. For the others one-third of drugs are imported drugs. However, raw materials of drug production in Thailand are mostly imported.

(1) Drug quality

Development of strategies and approaches for drug quality assurance are stipulated by the Drug Committee under the Drug Act.

Quality of locally produced generic drugs is very important factor influencing the acceptance of physicians and consumers. There were a number of dissolution and bioequivalence studies on locally produced drugs such as anti-inflammatory groups.

(2) Drug research and development

Drug research and development in Thai are limited to study on quality of drugs because of budget deficiency, shortage of manpower, etc.

(3) Drug procurement and distribution

Drugs are distributed in pharmacies, hospitals, clinics, and others. There are several problems in the process:

- Need to strengthen PTC and provincial drug-purchasing group strategies in order to achieve good quality of drugs at reasonable price.
- Deficient of information concerning in drug market.
- Inadequate to support education for consumers.
- Overlap of professional responsibilities.

(4) Drug price control

Drug pricing in Thailand is controlled through the following mechanism:

- Market mechanism allowing free competition.
- Direct price control under price fixing and Antitrust Act enforced by Ministry of Commerce
- Medium pricing designated for the sale of essential drugs in public hospitals.
- Patented drug pricing control designated by the Committee on Patent Drug Act.

(5) Impact from international economy:

- Agreement on intellectual properties.
- Free trade agreement.

2.1.4 Drug information

Drug information is essential as a base for decision making on the part of consumers, medical professions, and drug regulatory authorities. It is thus considered as important as the quality, safety, and efficacy of drugs. Information support of drug control and research and development (R&D), although plentiful, are scattered and difficult to be retrieved. Some information is inadequate especially those on behaviors of consumers, health professionals, and drug manufacturers.

2.1.5 Organizational and legislative infrastructure

The organizational and legislative infrastructure of the Thai drug system can be divided into two parts.

(1) Monitoring and control part

The Thai FDA is responsible for the implementation of drug control under three Acts i.e., Drug Act, Narcotic Act, and Psychotropic Substance Act. It is also responsible for development of a medium price system under the procurement regulation stipulated by the Office of the Prime Minister.

Office of the Permanent Secretary of the MOPH is responsible for enforcement of Measure of Efficiency improvement on DSM in 1999 and Bureau of Inspection under MOPH is responsible for monitoring and evaluation at the provincial level and hospital level following the measure.

Ministry of Commerce is responsible for the enforcement of price fixing, Antitrust Act, and Patent Act.

Office of the Prime Minister is responsible for Consumer Protection Act and drug procurement regulations.

The Healthcare Accreditation Institute is responsible to develop the quality of hospital services, disseminate knowledge management, create network and partnership, and evaluate and assure the quality of hospital services.

Professional council namely medical, dental, pharmacy, and nursing councils are responsible for the enforcement of Medical Profession Act, Dental Profession Act, Pharmacy Profession Act, and Nursing Profession Act.

(2) Supportive and promotive part

The Thai Food and Drug Administration (FDA) coordinates and supervises activities under the national drug committee including the provision of public and professional education.

Office of Permanent Secretary supervises the selection, procurement, storage, and distribution of drugs in the hospitals under the MOPH.

NHSO is responsible to support mediation safety information to the hospitals both in public and private hospitals.

Universities and academic institutions, particularly the schools of medicine and pharmacy, carry out research on drugs and disseminate drug information.

2.1.6 Traditional and herbal medicine

There are two approaches for the development of this system. First approach, attempts to develop the process of selection, production/import and distribution of traditional medicine according to the Thai traditional medicine texts. Second approach, some herbal medicines are developed through scientific studies, mostly single herbs.

2.1.7 National Drug Policy

The policy was revised and its third version was approved in 2011. NDP is created to guide the total development of the drug system. The goal of NDP is that Thai people can access to essential drugs, rational use of drugs, and self-reliance on drugs. Major development which followed 4 strategies of NDP comprised of (1) accessibility of drugs, (2) rational use of drugs, (3) development of pharmaceutical industries, biomaterials, and herbals for self-reliance on drugs, and (4) development of drug control system for quality assurance, effectiveness, and safety of drugs (National Drug Committee, 2011).

2.2 Provincial level (Office of the Permanent Secretary, 1999; Bureau of Inspection and Evaluation, 2010)

Drug management committee in provincial level is appointed for stipulation of policy in accordance with the MOPH. The committee is responsible to select and goup purchasing of drugs at provincial level including consideration of quality of

drugs, monitor the reports related to DSM, and inspection and evaluation of the DSM at the government hospitals.

2.3 Hospital level (Office of the Permanent Secretary, 1999)

For the operation of DSM at hospital level following the measure of efficiency improvement on DSM in 1999, the objective was to develop DSM in government hospitals under MOPH. In sub-system of DSM, selection, procurement, distribution, and use of drugs efficiency mean well-being, good quality, saving cost, and rational prescribe of drugs.

2.3.1 The principles of DSM stipulated by MOPH were as follows.

(1) Holding the relevant purchasing regulations. They are the regulation of the Office of the Prime Minister on the supply, the regulation of the MOPH on drug and non-drug procurement and related policy to drug management of MOPH.

(2) Planning by the personnel who involve with drug use for group purchasing in drug management. Committee is formed at all level.

(3) Decision making of medical supply purchasing must based on corrected information of the quantities and prices.

(4) Development of information system on the reference price which can be used as the base price to make a decision in purchasing, monitoring, and accountability.

(5) Hospital drug list is the effective list. This list, minimum drug items as necessary and information on efficiency, quality, safety, and price of drugs, is used for a decision making of drug selection.

(6) Efficient drug procurement system increased the power of bargaining for the group purchasing process at provincial level. The regulation on appropriately drug quality selection and increasion of drug procurement efficiency will be able to be stipulated.

(7) Efficient drug inventory management system will prompt a better drug and decrease drug inventory for cost reduction of reserved drugs.

(8) Drug prescribing is appropriate and rationale. Feedback system of drug information to physicians is performed. Monitoring and evaluation

system of drug use including Therapeutic Drug Monitoring, Drug Use Evaluation, and feedback is also performed.

(9) A reporting system for monitoring and evaluation from regional and central sectors is periodically performed together with the inspection from the outside agencies such as the Office of the Auditor General of Thailand.

2.3.2 The guideline of measurement of efficiency improvement on DSM in 1999 was shown in Table 2.1.

Table 2.1 The guideline of measurement of efficiency improvement on DSM 1999

Issues	**Principles**	**Targets**
1. Management of drugs (and medicinal products)	1.1 Health personnels who involved in drug usage must participate in DSM management at all levels as a committee. 1.2 The committee is responsible to - stipulate the drug policy. - monitor the DSM following the regulation and the measure. - evaluate and resolve the problems involving drugs. - report the results of DSM according to report form.	(1) Committee separated in two levels. - Provincial level: provincial drug committee - Hospital level: PTC (A meeting of PTC is not less than 3 times/year and record the meeting clearly for inspection)
2. Drug need verification	2.1 Director of hospitals/ A head of pharmaceutical section are responsible to: - provide a drug purchasing plan. - propose information data of drug purchasing plan for permission.	1. Drug purchasing annual plan. 2. If there is any improvement of purchasing plan, the plan must be reconsidered by the committee.

Table 2.1 The guideline of measurement of efficiency improvement on DSM 1999 (Cont.)

Issues	Principles	Targets
3. Hospital formulary	Director of hospitals/ A head of hospital pharmacy are responsible to: 3.1 reduce the number of drugs in hospital. 3.2 increase proportion of drugs listed in NLEM to these listed in the hospital drug list.	(1) Number of drug listed in hospital drug list: - regional hospitals $\leq$ 700 items, - general hospitals $\leq$ 550 items, and - community hospitals $\leq$ 375 items. (2) The proportion of drug listed in NLEM to those listed in hospital drug formulary: - regional hospitals $\geq$ 70%, - general hospitals $\geq$ 80%, and - community hospitals $\geq$ 90%.
4. Selection of drugs	PTC is responsible to: 4.1 control the rate of increasing the number of drug listed in hospital formulary. 4.2 limit the number of drugs which have the same generic name.	(1) If 1 item of drug is additionally proposed to the hospital formulary, 1 item of other drug should be taken off except for a new drug group which has not been use. (2) The propose of new drugs into hospital formulary is performed not more than 1 time per year.

Table 2.1 The guideline of measurement of efficiency improvement on DSM 1999 (Cont.)

Issues	Principles	Targets
		(3) Drugs with the same generic name should be selected to use in hospital only 1 item according to dosage form and strength of drug. (4) Drug in the same group or having similar pharmacological activity should be selected not than 2 items.
5. Procurement and quality assurance	Director of hospitals/ A head of hospital pharmacy are responsible to: 5.1 purchases more drugs listed in NLEM by using government budget and hospital budget. The Director of Provincial Public Health Office is responsible to this process. 5.2 purchase drugs by group purchasing or bargaining process of all hospitals in each province.	(1) Drug purchasing on NLEM using hospital budget of each hospital: - regional hospitals $\geq$ 60%, - general hospitals $\geq$ 70%, and - community hospitals $\geq$ 80%. (1) The committee at regional and provincial level is set up. (2) Hospital drug lists are stipulated by the committee at each level.

Table 2.1 The guideline of measurement of efficiency improvement on DSM 1999 (Cont.)

Issues	Principles	Targets
	5.3 assure the quality of purchased drugs.	(3) Drug lists which have high value on top 100 are stipulated for target of drug procurement. Exception is made for drugs produced by GPO. (1) The criteria of selected drug quality are specified
6. Production	6.1 Drugs are produced by regional hospitals and general hospitals to support community hospitals or centralized drug production is performed.	Regional hospitals and general hospitals produce drugs to support community hospitals with profit not more than 10-20 percent. Budget can be rearranged between hospitals in each province.
7. Storage and distribution	Pharmaceutical department of each hospital is responsible to: 7.1 decrease amount of drug storage in each hospital. 7.2 decrease amount of drug storage or remaining drugs on wards.	(1) Drug inventory is not more than 3 months. (2) Drugs are storaged in the community hospitals as reserved drug stock for distribution to PCUs. (3) Unit Dose System or Daily Dose System is used in wards.
8. Use of drugs	The Director of hospitals are responsible to:	(1) Physicians prescribe drugs using GN.

Table 2.1 The guideline of measurement of efficiency improvement on DSM 1999 (Cont.)

Issues	Principles	Targets
	8.1 support the use of GN by PTCs. 8.2 support rational drug use.	(2) Hospitals state the policy about certain time of automatic stop drug prescribing especially for antibiotic drugs. (3) Hospitals monitor and evaluate the drug use especially in expensive drugs, High Alert Drugs (HAD), or drugs with severe Adverse Drug Reaction (ADR).

2.3.3 The operation supports of DSM

(1) Department of Medical Science, FDA, and regional hospitals are responsible to operate the development of drug quality assurance and inform the information about drug analysis and drug quality together with criteria of qualified drug selection.

(2) The Drugs and Medical Supplies Information Center (DMSIC) is responsible to:

- Update the list of reference of drug price every 3-4 months for hospitals to make a decision in drug purchasing.
- Gather and analyze the progress DMSIC report and subsequently propose to MOPH.
- Consult for operating of drug system management (DSM).

2.3.4 Monitoring and evaluation of DSM

(1) MOPH supports the operation following policy and measure of DSM together with self monitoring and evaluation by the hospitals and Provincial of Public Health.

(2) Data Management Service Information Center is responsible to:

- Monitor and evaluate the operation following DSM by using appropriate indicators.

- Present the operation progress reports and evaluation results to MOPH for appropriate improved policy.

(3) The Bureau of Inspection and Evaluation under MOPH is responsible to monitor, evaluate, and solve the problems of DSM operation for target achieving.

(4) The committee of coordination and development is responsible to coordinate, monitor, and give suggestion to MOPH for the DSM operation.

Several organizations of both public and private sectors are involved in DSM operation at all three levels. The operations of DSM at each level are different following the function of the organizations or institutions. In national level, many organizations operate the DSM with the key issues about drug industry, drug registration, and herbal medicines differ from the key issues of DSM operation at provincial and hospital level. For the provincial level, the Provincial Public Health Office coordinate, monitor, inspect, and evaluate as well as to support the DSM operation of the government hospital in its region. When considering the key issues of DSM at hospital level, it is found that eight key issues of the measure influence to the performance of DSM and conform to the operation in national level. Thus, all organizations at all three levels focused on the same target which are the NDP achieving and the DSM performance efficiency development.

3. Quality indicators (QIs) for monitoring and evaluation of Drug System Management (DSM) performance at the community hospitals under MOPH.

(1) Bureau of Inspection and Evaluation under MOPH

The Bureau of Inspection and Evaluation is responsible to impose the policy for regional level by the inspector, sub-inspectors, public health supervisor and

assistant supervisors of the Ministry of Public Health by using E-inspection report and hospital visit. They inspect community hospitals in the provincial level two times a year with the responsibility in monitoring, examining, and reporting the operation progress. The operation must follow the involving roles and regulations for the purposes of cost-saving, worthiness, benefits, and assessing achievement of the government works. The E-inspection report consisted of 9 quality indicators as follows.

(1.1) Number of drug items in hospital formulary

(1.2) Number of essential drugs (ED) in hospital formulary

(1.3) Number of ED per non-ED

(1.4) Regional drug co-procurement

(1.5) Provincial drug co-procurement

(1.6) Purchasing drugs from the GPO

(1.7) Purchasing drug follows the NLED

(1.8) Value of inventory drugs

(1.9) Drug inventory rate

(2) DMSIC under MOPH

The DMSIC has been responsible to collect, analyze, and report the DMSIC data since 1999 to present. This center has monitored and evaluated the hospital operations following five items of DMSIC report as follows.

(2.1) Number of drug items in hospital formulary

(2.2) Number of ED per NED

(2.3) Provincial drug group purchasing value

(2.4) Purchasing value of drugs according to the NLED

(2.5) Drug inventory rate

(3) The Provincial Public Health Office affiliated with the Office of the Permanent Secretary under MOPH

The province level leads by the Director of the Provincial Public Health. Drug management committee in provincial level is appointed for stipulation of policy in accordance with the ministry and regional level. Policy implementation and

coordination between working officers are also involved. The group purchasing committee in provincial level is also set up for bargaining and selecting drugs. In addition, the drug quality consideration committee is also appointed to select the qualified drug company and the offered drug prices. Apart from these committees, the drug management monitoring and developing committee is responsible for monitoring and developing of drug management in the provincial level together with setting up of provincial drug list.

The Provincial Public Health Office is responsible for monitoring and evaluation of drug management at the hospital level, by the official (internal auditor) who is responsible for DSM in Provincial Public Health Office called the internal audit committee which work by the name of the drug management monitoring and developing committee. The internal audit committee inspects the DSM operation at the community hospitals two times a year. Evaluation indicators used depend on the internal auditor to be stipulated together with E-inspection and DMSIC reports.

(4) The National Health Security Office (NHSO)

The NHSO stipulated aims to access to quality, efficacy and safety of drugs, and rational use of drugs. NHSO strategy of DSM composed of; firstly, developing of procurement policies for monitoring drug access and organizing the drug distribution and medical supplies necessary for the person having the right to universal health insurance system. Secondly, developing of drug information systems to facilitate the utilization of development and monitoring of rational drug use. Thirdly, supporting of quality assurance of drug use in Universal Coverage (UC). Fourthly, creating of the participation of other sectors in the role and participation in drug management system. And finally, enhancing of efficiency and fairness in procurement and compensation for medicine in security. The NHSO developed safety medication indicators for assessing the DSM in the hospitals in 2011 as follows.

(4.1) Drug utilization evaluation/ Drug utilization review (DUE/ DUR)

(4.2) Adverse drug reaction/Adverse drug event (ADR/ADE)

(4.3) High alert drug (HAD)

(4.4) Antibiotic smart use (ASU)

(5) The Healthcare Accreditation Institute 2011

The Healthcare Accreditation Institute is a public organization which is responsible to the Hospital Accreditation (HA). The roles of HA were as follows; 1) to develop the quality of hospitals, (2) to develop and disseminate knowledge management, (3) to create network and partnership, (4) to support the quality of hospitals, and (5) to evaluate and assure the quality of hospitals by using 12 quality indicators as follows.

(5.1) Number of drug prescription: out-patient

(5.2) Prescribing error: out-patient

(5.3) Processing error: out-patient

(5.4) Dispensing error: out-patient

(5.5) Number of drug prescription: in-patient

(5.6) Prescribing error: in-patient

(5.7) Processing error: in-patient

(5.8) Dispensing error: in-patient

(5.9) Effecting of medication error

(5.10) Drug utilization evaluation/ Drug utilization review (DUE/ DUR)

(5.11) Adverse drug reaction/Adverse drug event (ADR/ADE)

(5.12) High alert drug (HAD)

(6) The Pharmaceutical System Research & Intelligence Center (PSyRIC)

The PSyRIC is an academic institution to develop "Hospital Drug System Performance Indicators" in 2007. The PSyRIC works with drug system network such as Health System Research Institute, Thai Health Promotion Foundation, Thai Drug Watch, etc to develop 18 quality indicators for assessing drug system performance as follows.

(6.1) Duration of drug prescribing: out-patient (for shortest time)

(6.2) Duration of drug prescribing: out-patient (for all day)

(6.3) Prescribing error: out-patient

(6.4) Transcribing error: out-patient

(6.5) Pre-dispensing error: out-patient

(6.6) Dispensing error: out-patient

(6.7) Pre-administration error: out-patient

(6.8) Administration error: out-patient

(6.9) Prescribing error: in-patient

(6.10) Transcribing error: in-patient

(6.11) Pre-dispensing error: in-patient

(6.12) Dispensing error: in-patient

(6.13) Pre-administration error: in-patient

(6.14) Administration error: in-patient

(6.15) Percentage of severity ADR

(6.16) Number of repeated ADR

(6.17) Drug inventory rate

(6.18) Number of drug shortage

(7) Bureau of Health Administration under MOPH

The Bureau of Health Administration is a public organization which developed the drug safety standard for monitoring and assessing the DSM at the hospitals affiliated with MOPH. The purpose of this standard was to assess the drug safety of patients at the hospitals under MOPH. It responses the WHO about patient safety. The results of this standard are benefit for providers at MOPH to present the situation of development of drug safety in the hospitals and to use data for planning and supporting for pharmaceutical at the hospitals.

The drug safety standard was developed by the Bureau of Health Administration in 2011. The standard composed of ten issues and each of issue consisted of five levels for assessing the drug safety process as follows.

Issues 1: Management of drug safety system at the hospitals

Goal: To stipulate policy, develop the drug safety system to assure that the patients should be safe by co-operation in multidisciplinary as follows:

Level 1	Not operate.
Level 2	Can operate some topics at level 3.
Level 3	Can operate all topics including. (1) There is a clearly system or guideline to reduce medication error on drug system. (2) There is a system for incident report and near miss events; and conclusion the report for the stakeholders every month. (3) There is a continuously planning for operations responding a policy of drug quality and drug safety related to drug issues. (4) There is a written policy about drug quality and drug safety at the hospital. (5) There is a manual/ guideline of drug safety for patient safety; to convey and distribute the manual/ guideline to staffs which relevant to this operation. (6) There is a clear orientation for new staffs at department of pharmacy. (7) There are the meeting for the pharmacists of hospital for assessing risk of department of pharmacy and to prepare the account of drug risk for planning and protecting the risk. (8) There are verification of the ADR and drugs interaction.
Level 4	Can operate all topics at level 3 and some topics at level 5.
Level 5	(1) There are all operations at level 3, and (2) There are committees or multidisciplinary to monitor problems, to plan and operate, and to continuously improve the problems of drug quality and drug safety. (3) There is a staff at drug room relating the preparation of chemotherapy drug and giving consultation for acquired immunodeficiency syndromes (AIDs) and tuberculosis patients with health checking up every year. (4) There is an information system (intranet) for supporting and promotion of the drug safety for patients such as perceiving of a diagnosis to perform drug dispensing with an instruction on drug use. (5) There is a program to check the ADR and drug interaction.

	(6) It was not found the problem involving the use of drugs which influencing to patient death or patients admission in a hospital during the last 2 years. (7) There was no infected staff at drug room caused by patients who received service in the last year.

Issues 2: Structure and environment for supporting to create the drug safety

Goal: To manage the physical structure, environment of work, and appropriate tools for reducing risk and accident to assure and support on creation the drug safety.

Level 1	Not operate.
Level 2	Can operate some topics at level 3.
Level 3	Can operate all topics including. (1) There is a system for separation of dangerous drugs as a waste. (2) There is a consultation place with good ventilation system to protect the respiratory tract infection. (3) There is a management system related to the chemotherapy involving place of production, preparation equipment, storage, transfering, protection between delivery, disposal, and cleaning system in case of drugs spilling. (hospital which giving a service of the chemotherapy) (4) There are suitable clean locations of drug dispensing, drug inventory, drug production which is not an obstacle of practices related to the medication error.
Level 4	Can operate all topics at level 3 and some topics at level 5.
Level 5	(1) There are operations of all topics at level 3, and (2) There is a system of infectious and hazardous waste disposal which is completely separated from general waste disposal. (3) There is a practice of movement in drug room or table top practice following the set up planning in case of emergency event at least 2 years per time. (4) There is no report on the risk of drugs causing patient death or

	disability, patient life saving from any reason caused by physical structure, environment, and tools, or no practices following stipulated standard procedure in the last 2 years.

Issues 3: Development of personnel competency

Goal: To manage the system and to develop human resource on drug to increase competency for supporting on creation the drug safety.

Level 1	Not operate.
Level 2	Can operate some topics at level 3.
Level 3	Can operate all topics including. (1) There is a plan of personnel development for department of pharmacy following the training needs of the hospital. (2) There are pharmacists of pharmacy department participated in meeting and training for academic restoration every year or executed continuing education which all pharmacists must not less than 20 CPE credits per year. (3) All personnel in department must have participate academic training/ meeting not less than 1 time per year. (4) There is a portfolio of all personnel in training/ meeting. (5) A head of pharmacy department extended a short course training in field of administration.
Level 4	Can operate all topics at level 3 and some topics at level 5.
Level 5	(1) There are operations of all topics at level 3, and (2) There is an assessment of the individual performance in accordance with competency KPI of each position and function. (3) There is continuing education in master degree or approval letter or diploma of profession council not less than 10 percent of all pharmacists with certain official function. (4) There is an assessment job of descriptions and sufficient amount of man power of the hospital, and ready to operate and improve every year.

Issues 4: Drug dispensing for out-patients

Goal: To perform the accurate, fast, quality, and standard services to patients. The patients can take the right drugs with safety following STG, and the risk of drugs which may occur can be protected.

Level 1	Not operate.
Level 2	Can operate some topics at level 3.
Level 3	Can operate all topics including. (1) Pharmacists directly see the copy or actual drug order of physician. (2) Drug labels are composed of complete information: patient name, drug name, strength, method to use of drugs, caution or auxillary label. (3) There is an inspection on pre-dispensing of drugs by the pharmacists. (4) There is delivery of drugs by pharmacists especially in official time. (5) There is communication with the patients using a clearly principle of prime question. (6) There is the record of prescription errors, pre-dispensing errors, dispensing errors, and is presented to the meeting for problem improvement. (7) There is a proactive inquiry system for dispensing errors. (not only for defensive action and waiting to inform or report)
Level 4	Can operate all topics at level 3 and some topics at level 5.
Level 5	(1) There are operation of all topics at level 3, and (2) There is the drug dispensing system by the pharmacists to all patients. (3) There is a development of problem improvement of medication error. (4) Pharmacists can assess the data, especially the data of each patient before dispensing of drugs. (5) 80 percent of the patients received drugs within 20 minutes since handing in drugs prescription at the drug dispensing room and no drug prescription which the patients received drugs more than 60 minutes. (6) There is no dispensing errors in case of HAD of out-patients. (7) There is no incident of dispensing errors which effecting to the patient death, disability or severe condition which needs life saving.

Issues 5: Drug Dispensing for in-patients

Goal: To distribute drugs with right system; to prevent the risk and medication error of drugs. The patients can take the right drugs with safety and following STG.

Level 1	Not operate.
Level 2	Can operate some topics at level 3.
Level 3	Can operate all topics including. (1) Pharmacists directly see the copy or actual drug order of physician. (2) There is a pharmacist to verify drugs before dispensing. (3) There is created patient profiles for using in monitoring the problems. (4) There are explored and recorded systems of prescribing error, dispensing error, and administration error to present to the committee and to stipulate the guideline for improving the problems. (5) There is a stipulation of the number and items of drugs stored in each ward by multidisciplinary. (6) There is a drug management system for using of drugs during the treatment of patients in the hospital.
Level 4	Can operate all topics at level 3 and some topics at level 5.
Level 5	(1) There are operations of all topics at level 3, and (2) There is a verification system of drugs remaining in ward for recalling. (3) There is a dispensing of drugs to patients for home medication by pharmacists in all cases. (4) There is a dispensing system related to unit dose or one day dose covering all of the hospitals. (at least for drugs in tablet and injection dosage forms) (5) Drugs are dispensed in each ward within 120 minutes and the drugs with stat dose must be dispensed in each ward within 30 minutes after the bill of lading or drug prescription are handed in the pharmacy unit. (6) There is no dispensing errors in case of HAD of in-patients. (7) There is no incident of dispensing errors which effecting to the patient death, disability or severe condition which needs life saving.

Issues 6: Drug counselling service for out-patients

Goal: To give a pharmaceutical care for out-patients and to assure that the patients can correctly use of drugs in accordance with drug order, and be safety.

Level 1	Not operate.
Level 2	Can operate some topics at level 3.
Level 3	Can operate all topics including. (1) There is a clear stipulation criterion for counselling of drugs to patients. (2) There is counselling of drugs for all patients in case of specific drugs which special technique is needed. (3) There is a patient profile to collect, monitor and consult the utilization of drugs continuously. (4) There is a manual for counselling of drugs following the stipulated criteria. (5) There is participation of multidisciplinary in health education or counselling of drugs in special clinic for chronic patients.
Level 4	Can operate all topics at level 3 and some topics at level 5.
Level 5	(1) There are operations of all topics at level 3, and (2) There is a proper room for drug counselling. (3) Chronic patients continuously receive drug counselling not less than 3 times or patients can be controlled in regular stage. (4) There is a system for assessing the knowledge and satisfication of patients with regular stage. (5) Number of chronic out-patients who received the drug counselling and returned to the hospital is not less than 10 percent.

Issue7: Pharmaceutical care in ward

Goal: to provide the pharmaceutical care for in-patients with multidisciplinary; the patients received correct and safety drugs which are appropriate for patients state following the treatment guideline.

Level 1	Not operate.
Level 2	Can operate some topics at level 3.
Level 3	Can operate all topics including. (1) There is a clear stipulation criterion for monitoring the problems of drugs in wards. (2) There is a clearly collected the data related to administration error. (3) There is a collection form to monitor problems involving the use of drugs by pharmacists. (4) There is a creation for discharge counselling in chronic patients. (5) There is a system of knowledge management of pharmacists about case studies related to drug problems to prevent of reoccurance of the problem.
Level 4	Can operate all topics at level 3 and some topics at level 5.
Level 5	(1) There are operations of all topics at level 3, and (2) There is a providing of the responsibility of pharmacists for monitoring the problems involving drug use in ward. (3) Pharmacists participated in health care team for in-patients as multidisciplinary characteristic. (4) Pharmacists can write pharmacist note/ progress note or patient chart together with multidisciplinary team. (5) There is a service to monitor drug level in blood of patients receiving drugs with narrow therapeutic index or in case of drugs which afffect to nephropathy patients or deficienncy function of kidney or surveillance system to prevent the problems of drug use in these groups of drugs. (6) There is an example case of the results of pharmaceutical care with multidisciplinary team that can help patients for drug safety. (7) There is no accuse and request about the problems of patients related to the use of drugs which can be prevented in the last year.

Issue 8: Monitoring ADR from the use of drugs and health products

Goal: to monitor the ADR following effective warning system for creating drug safety of patients.

Level 1	Not operate.
Level 2	Can operate some topics at level 3.
Level 3	Can operate all topics including. (1) There is a monitoring of spontaneous APR. (2) There is a creation of APR report for all cases found. (3) There is an APR assessment following Naranjo's agorithm, WHO criteria or other system of assessment method by the pharmacists. (4) There is a system of medical history accessing and monitoring of patients in case of prescribed antihistamine, steroids or tracer agents, and others. (5) There is an APR card in case of patients with ADR and a recorded history system. ADR in medical record can be clearly observed.
Level 4	Can operate all topics at level 3 and some topics at level 5.
Level 5	(1) There are operations of all topics at level 3, and (2) There is a clear stipulation of drug items monitored APR in intensive type, especially, drugs involving HAD. (3) There is an operation of ADRM by multidisciplinary team. (4) There is no re-ADR found in any patients causing from deficiency of system at the hospital in the last 2 years.

Issue 9: Drug use evaluation

Goal: to provide the system related to reviewing, assessment, and development of prescribed drugs for appropriate use of drugs.

Level 1	Not operate.
Level 2	Can operate some topics at level 3.
Level 3	Can operate all topics including. (1) There is an assessment of drug use in quantitative data and the conclusion report is provided. (2) There is an operation of involving physician to create criteria of DUE. In case of monitoring of quantitative data, it is found that the problems of drug use may be occurred or high use of drugs.

	(3) There is DUE as qualitative data on some drugs which may cause problems at the hospitals.
Level 4	Can operate all topics at level 3 and some topics at level 5.
Level 5	(1) There are operations of all topics at level 3, and (2) There is a presentation of the results of DUE to the hospital committee for considering of the practice guideline to improve problem in case of unappropriate use of drugs. (3) There is a clear stipulated and provided practice guideline to be used as treatment guideline at the hospitals especially in case of unappropriate use of drugs. (4) There is DUE continuously operated as qualitative data of hospitals every year.

Issue 10: Service of drug information

Goal: to provide drug information for right decision about drugs.

Level 1	Not operate.
Level 2	Can operate some topics at level 3.
Level 3	Can operate all topics including. (1) There is assigned pharmacists with responsibility in drug information service. (2) There is the drug information service continuously and regulary openned for service. (3) There is an obvious record following the standard of drug information service. (4) There is a news letter or other media to regularly generate drug information. (5) There is a creation of the drug information to support the service of medical personnel.
Level 4	Can operate all topics at level 3 and some topics at level 5.
Level 5	(1) There are operations of all topics at level 3, and (2) There is a clearly set up unit or center of drug information.

	(3) There is a taking of information technology to provide the program of drug data and/or to access drug data base through internet at all the time when the service system is opened. (4) There is a system of satisfaction assessment on data which continuously serviced. (5) There is a proactive project affected by drug information services of supporting the drug safety of patients. (6) There is clearly verifing or assuring the data by the committee for servicing system.

Issue 11: Drug preparation of the hospital

Goal: to produce the quality and standard drug preparation for servicing to patients.

Level 1	Not operate.
Level 2	Can operate some topics at level 3.
Level 3	Can operate all topics including. (1) There is an obvious responsible pharmacist for the operations. (2) There is a creation of master formula of all drug preparations in hospital formulary. (3) There is a providing of the working formula and drug label with correct information of production at all times and the feedback data can be verified. (4) There is creation of SOP of principle process of drug production at the hospitals and always be improved for update data. (5) There is a record monitoring of production process in all steps by the pharmacists. (6) There is a verification of the quality control of drugs for contemporary preparing of water for drug production, contamination, microorganism etc.
Level 4	Can operate all topics at level 3 and some topics at level 5.
Level 5	(1) There are operations of all topics at level 3, and (2) There is a random verification of drug quality analysis at least 1 time

	per year. (3) There is a preparation of drug with standard verification of COA following the criteria stipulated for all samples. (4) There is a verification of quality analysis of drugs in some formularies of the hospitals (5) There is an appropriate storation of the prepared drugs concerning stability of drugs for developing of drug formulary. (6) There is no report drug risk that affects the patients to admit in the hospitals causing from prepared drug preparations.

Issue 12: Drug slection systen of the hospitals

Goal: to provide the drug selection system based on evidence base and to use of drugs at the hospitals effectively.

Level 1	Not operate.
Level 2	Can operate some topics at level 3.
Level 3	Can operate all topics including. (1) There is a creation of formulary of drug items of hospital and the formulary updated every year. (2) There is a stipulation of clear criteria for consideration of drugs to take in and out of drug formulary. (3) There is a regulary meeting of PTC committee not less than 2 times per year. (4) There is a system of administration of sample drugs and assessment for evidence based considering of drug information before considering to present drugs into the hospital formulary. (5) There is a providing of the drug monograph for consideration in drug selection process at the meeting of PTC committee.
Level 4	Can operate all topics at level 3 and some topics at level 5.
Level 5	(1) There are operations of all topics at level 3, and (2) There are drug items in accordance with NLED not less than 80 percent of the hospital formulary.

	(3) There is information of drug risk or medication error for utilization in selection of the drugs in-out of hospital formulary every time of updating. (4) Physician cannot prescribe the drugs which did not listed in hospital formulary to patients.

Issue13: Purchasing and inventory of drugs

Goal: to provide the effective drug management following the stipulated rules or regulations and to have quality drugs for servicing to the patients.

Level 1	Not operate.
Level 2	Can operate some topics at level 3.
Level 3	Can operate all topics including. (1) There is an approval to purchase drugs before ordering of drugs. (2) There is a system to verify and perform quality control of drugs and products, especially, the recorded and monitored temperature at dispensing room, store room, and refrigerator. (3) There is a proposition to destroy, transfer, exchange of drug expired, drug deterioration or not essential to use every year which found problems. (4) There are committees to select company from which drugs are purchased. (5) There is a group purchasing in provincial and region levels.
Level 4	Can operate all topics at level 3 and some topics at level 5.
Level 5	(1) There are operations of all topics at level 3, and (2) There is a system of regulary registering and assessing the trading partner of hospitals less than 1 time per year. (3) There is a value of drug inventory not less than 3 months when compared with the value of drug use in each year. (4) There is no drug shortage for dispensing to patients except the company cannot supply to the hospital. (5) There is no drug expired or drug deterioration in drug inventory.

4. Quality indicators (WHO, 1994)

Quality indicators (QIs) are an important tool used to measure the performance. It can be used to assess and evaluate the present situation of organization. Development of quality indicators is the importance of defining criteria. A set of quality indicators provided a common approach for quality indicator development in the field of DSM using by expert group. It was stipulated that quality indicators should be developed according to the following principles:

Usefulness for action: the data provided from the quality indicators should primarily help to strengthen DSM and NDP, and secondarily help to promote goals and targets set up at the provincial level. The quality indicators should be useful for administration, decision-making and action at the level where the data are collected.

Clarity: the quality indicators should express a single idea that is generally agreed to be important.

Ease of generation and measurement: the data should, as far as possible, result from the regular data collection system. If the quality indicator requires an additional survey, this should be within.

Consistency and validity: the quality indicators should be proven of capable of being recorded throughout the system with an acceptable degree of validity and reliability.

Relevance: the quality indicators should serve to measure progress towards the goals, objectives and targets stated in NDP of Thailand.

Ease of comparison: the quality indicators should, when feasible, provide data that can be compared with specific norms and objectives.

5. Delphi technique

The Delphi technique is a decision making technique developed as part of an Air Force sponsored by Rand Corporation study in the early 1950's. The Delphi technique seeks to achieve a consensus among group members through a series of questionnaires.

The questionnaires are answered anonymously and individually by each member of the group. The answers are summarized and sent back to the group members along with the next questionnaire. This process is repeated until a group

consensus is reached. This usually only takes two iteration, but can sometimes take as many as six rounds before a consensus is reached.

The Delphi technique is based on structural surveys and makes use of the intuitive available information of the participants, who are mainly experts. Therefore, it delivers qualitative as well as quantitative results and has beneath its explorative, predictive even normative elements. There is not the one Delphi methodology but the applications are diverse. There is agreement that Delphi is an expert survey in two or more 'rounds' in which in the second and later rounds of the survey the results of the previous round are given as feedback. Therefore, the experts answer from the second round on under the influence of their colleagues' opinions. Thus, the Delphi method is a relatively strongly structured group communication process, in which matters, on which naturally unsure and incomplete knowledge is available, are judged upon by experts. (Häder and Häder, 1995)

Wechsler (1978) characterises a Standard-Delphi-Method in the following way: it is a survey which is steered by a monitor group, comprises several rounds of a group of experts, who are anonymous among each other and for whose subjective-intuitive prognoses a consensus is aimed at. After each survey round, a standard feedback about the statistical group judgement calculated from median and quartiles of single prognoses is given and if possible, the arguments and counterarguments of the extreme answers are fed back. This sounds a bit complicated but the essentials are:

- Delphi is an expert survey in two or more rounds.

- Starting from the second round, a feedback is given (about the results of previous rounds).

- The same experts assess the same matters once more influenced by the opinions of the other experts.

Characteristics of Delphi are therefore specified as (Häder and Häder, 1995):

- Content of Delphi studies are always issues about which unsure respectively incomplete knowledge exists. Otherwise there are more efficient methods for decision-making.

- Delphi is judgement processes with unsure aspects. The persons involved in Delphi studies only give estimations.

- The participation experts involved on the basis of their knowledge and experience which are able to assess in a competent way. During the rounds, they have the opportunity to gather new information.

- Delphi tries to make use of self-fulfilling and self-destroying prophecies in the sense of shaping or even 'creating' the future.

Understanding the process

The Delphi is a group facilitation technique that seeks to obtain consensus on the opinions of experts through a series of structured questionnaires (commonly referred to as rounds). The questionnaires are completed anonymously by these experts (commonly referred to as the panellists, participants or respondents). The term participants will be used subsequently. As a part of the process, the responses from each questionnaire are fed back in summarized form to the participants. The Delphi is therefore an iterative multistage process designed to combine opinion into group consensus (Hasson et al, 2000). The initial questionnaire may also collect qualitative comments, which are fed back to then participants in a quantitative form through a second questionnaire. Alternatively, qualitative data can be collected through focus groups or interviews and used to inform a quantitative first round of the Delphi. As with all good surveys, pilot testing with a small group of individuals should precede implementation. After statistical analysis regarding group collective opinion, the results from the second questionnaire help in the formulation of the third quantitative questionnaire. This process is ongoing until consensus is obtained or the law of diminishing returns sets in. That is, responses are summarized between rounds and communicated back to the participants through a process of controlled feedback; this process is repeated until consensus is reached or until the number of returns for each round decreases.

The process gathers opinion without the need to bring panellists together physically. By using successive questionnaires, opinions are considered in a non-adversarial manner, with the current status of the groups' collective opinion being repeatedly fed back. This informs the group members of the current status of their collective opinion (Goodman, 1987) and helps to identify items that participants may have missed or thought unimportant. Therefore, the opportunity exists for participants to change their opinions (McKenna, 1994).

Identification and selection of the sample

The selection of the sample of experts involves nonprobability sampling techniques, either purposive sampling or criterion sampling. Here participants are not selected randomly, so representativeness is not assured. Rather, they are selected for a purpose, to apply their knowledge to a certain problem on the basis of criteria, which are developed from the nature of the problem under investigation. Purposive sampling is based on the assumptions that a researcher's knowledge about the population can be used to handpick the cases to be included in the sample (Polit and Hungler, 1997). These assumptions are founded on criteria and as Patton (1990) explains `the logic of criterion sampling is to review and study all cases that meet some predetermined criterion of importance'. Both techniques are similar to selective sampling procedures.

Once the sample is confirmed, the next stage involves the negotiation of access to information regarding the potential participants; and this is a process fraught with difficulties. Identification of the sample may need to be identified to help pinpoint those individuals who will have knowledge of the topic under study. Alongside this, secondary data may have to be accessed to aid identification of the sample. This brings further problems relating to access and authenticity, as databases containing addresses may be obsolete.

Once identified, the potential participants must be approached in an attempt to recruit them to the study. Some researchers target their sample without any prior notices: this approach may influence the response rate. In his study McKenna (1994) found that it was more advantageous to employ face-to-face interviews in the first round as this helped to increase the response rates in that and subsequent rounds. Although direct contact with the sample is time consuming, the nature of this contact can affect the results obtained. It should be noted, however, that these are criticisms that could be aimed at any qualitative study. However, the Delphi, unlike other methods, requires a continued commitment from participants being questioned about the same topic over and over again, using a slightly modified questionnaire each time. Therefore, as the Delphi is heavily dependent upon the sample having the time to commit to the process, it is also important that those who have agreed to participate, maintain involvement until the process is completed (Buck et al, 1993).

Delphi process

Theoretically, the Delphi process can be continuously iterated until consensus is determined to have been achieved. However, Cyphert and Gant (1971), Brooks (1979), Ludwig (1994; 1997), and Custer et al. (1999) pointed out that three iterations are often sufficient to collect the needed information and to reach a consensus in most cases. The following discussion, however, provides guidelines for up to four iterations in order to assist those who decide to use the Delphi process as a data collection technique when it is determined that additional iterations beyond three are needed or valuable.

Round 1: In the first round, the Delphi process traditionally begins with an open-ended questionnaire. The open-ended questionnaire serves as the cornerstone of soliciting specific information about a content area from the Delphi subjects (Custer et al, 1999). After receiving subjects' responses, investigators need to convert the collected information into a well-structured questionnaire. This questionnaire is used as the survey instrument for the second round of data collection. It should be noted that it is both an acceptable and a common modification of the Delphi process format to use a structured questionnaire in Round 1 that is based upon an extensive review of the literature. Kerlinger (1973) noted that the use of a modified Delphi process is appropriate if basic information concerning the target issue is available and usable.

Round 2: In the second round, each Delphi participant receives a second questionnaire and is asked to review the items summarized by the investigators based on the information provided in the first round. Accordingly, Delphi panellists may be required to rate or rank-order items to establish preliminary priorities among items. As a result of round two, areas of disagreement and agreement are identified (Ludwig, 1994). In some cases, Delphi panellists are asked to state the rationale concerning rating priorities among items (Jacobs, 1996). In this round, consensus begins forming and the actual outcomes can be presented among the participants' responses (Jacobs, 1996).

Round 3: In the third round, each Delphi panellist receives a questionnaire that includes the items and ratings summarized by the investigators in the previous round and are asked to revise his/her judgments or "to specify the reasons for remaining outside the consensus" (Ludwig, 1997). This round gives Delphi panellists

an opportunity to make further clarifications of both the information and their judgments of the relative importance of the items. However, compared to the previous round, only a slight increase in the degree of consensus can be expected (Jacobs, 1996).

Round 4: In the fourth and often final round, the list of remaining items, their ratings, minority opinions, and items achieving consensus are distributed to the panellists. This round provides a final opportunity for participants to revise their judgments. It should be remembered that the number of Delphi iterations depends largely on the degree of consensus sought by the investigators and can vary from three to five (Ludwig, 1994).

Time Requirements

Conducting a Delphi study can be time-consuming. Specifically, when the instrument of a Delphi study consists of a large number of statements, subjects will need to dedicate large blocks of time to complete the questionnaires. Delbecq et al. (1975), Ulschak (1983) and Ludwig (1994) recommend that a minimum of 45 days for the administration of a Delphi study is necessary. With regard to the time management between iterations, Delbecq et al. (1975) note that giving two weeks for Delphi subjects to respond to each round is encouraged.

Ludwig (1994) indicates “a drawback to Delphi was that the questionnaire method may slow the process greatly as several days or weeks may pass between rounds". More specifically, since developing the instrument, collecting the data, and administering the questionnaire are interconnected between iterations, ensuring Delphi subjects respond to the investigators on time does in many ways either promote or prohibit the ability of the investigators in analyzing the data, developing a new instrument based upon the prior responses, and distributing subsequent questionnaires in a timely fashion. These are challenging aspects of conducting a Delphi study and do require proper planning and management.

Data Analysis

Regarding data analysis, decision rules must be established to assemble and organize the judgments and insights provided by Delphi subjects. However, the kind and type of criteria to use to both define and determine consensus in a Delphi study is

subject to interpretation. Basically, consensus on a topic can be decided if a certain percentage of the votes falls within a prescribed range (Miller, 2006). One criterion recommends that consensus is achieved by having 80 percent of subjects' votes fall within two categories on a seven-point scale (Ulschak, 1983). Green (1982) suggests that at least 70 percent of Delphi subjects need to rate three or higher on a four point Likert-type scale and the median has to be at 3.25 or higher. Campbell and Sweeney (2002) reveal that the use of percentage measures is inadequate. They suggest that a more reliable alternative is to measure the stability of subjects' responses in successive iterations.

In the Delphi process, data analysis can involve both qualitative and quantitative data. Investigators need to deal with qualitative data if classic Delphi studies, which use open-ended questions to solicit subjects' opinions, are conducted in the initial iteration. Subsequent iterations are to identify and hopefully achieve the desired level of consensus as well as any changes of judgments among panellists. The major statistics used in Delphi studies are measures of central tendency (means, median, and mode) and level of dispersion (standard deviation and inter-quartile range) in order to present information concerning the collective judgments of respondents (Hasson, Keeney and McKenna, 2000). Generally, the uses of median and mode are favored. However, in some cases as manifested by Murray and Jarman (1987), the mean is also workable. Witkin and Altschuld (1995) questions the appropriateness of using the mean to measure the subjects' responses if scales used in Delphi studies are not delineated at equal intervals. In the literature, the use of median score, based on Likert-type scale, is strongly favored (Hill and Fowles, 1975; Jacobs, 1996). In 1996, Jacobs stated that "considering the anticipated consensus of opinion and the skewed expectation of responses as they were compiled, the median would inherently appear best suited to reflect the resultant convergence of opinion". The use of mode is also suitable when reporting data in the Delphi process. Ludwig (1994) specifically addressed that "the Delphi process has a tendency to create convergence, and though this was usually to a single point, there was the possibility of polarization or clustering of the results around two or more points. In these instances, the mean or median could be misleading".

In 2008, Campbell and colleague examined quality indicators to use for developing and applying in hospitals. Indicators based on clinical guidelines. Such indicators, for general practice, have been developed and disseminated widely in the National Health System (NHS) in the United Kingdom (UK) for four important clinical conditions (diabetes, coronary heart disease, asthma, and depression) using iterated consensus of Delphi technique in Table 2.2.

Table 2.2 Guideline driven indicators developed using an iterated consensus rating procedure

Round	Aim	Undertaken by	Criteria used
Round 1: Pre-selection	Selecting key recommendations	Small group of quality indicators developers (1-3 persons)	Outcome of care: - Patients' health (morbidity, mortality, health status) - Cost
Round 2: Rating and adding	Rating and adding key recommendations	Expert panel (8-10 persons)	- Patients' health - Cost - Sensitivity to change - Availability of data
Round 3: Reliability	Determining inter- and intra-rater reliability	Expert panel for the rating Research team for the analyses	-Kappa, rho
Round 4: Potential indicators	Getting set of potential indicators	Research team	- Cut off score: mean above mid of rating scale - Agreement among 80% of the panel members

Table 2.2 Guideline driven indicators developed using an iterated consensus rating procedure (Cont.)

Round	Aim	Undertaken by	Criteria used
Round 5: Reflection	Acceptability of indicators	Research team Laymen professionals	- Face validity

6. Literature reviews of DSM

Some studies have examined the hospital performance only on the selection, procurement, storage and distribution, and use of drugs in the hospitals. However none have focused on the DSM and the assessing tool for drug management which were essential to determine the efficiency of DSM in the hospital. It has been encouraging to see other concepts and studies following the key issues of DSM.

The Ministry of Health normally determined the types of drugs and dosage forms that are selected for use in a country (WHOa, 2004). WHO and partners have made progress in documenting current supply systems, developing of an assessing tools and training of materials. There are robust methods for selection of medicines through national essential medicines lists, and in some countries, through health insurance schemes. A major obstacle in development work is the medicine management systems. Such selections ensure that available financial resources are used wisely providing of a limited list of drugs and dosage forms that are appropriate to the health problems of a country or community and must confine with all levels of health care institutions, i.e. primary level of health care, secondary level of health care, and tertiary level of health care (WHO, 2008).

Thailand followed the 31st World Health Organization Assembly recommendations on drug system management. The first and the most important component of the Thailand's National Drug Policy (NDP) is the National List of Essential Drugs (NLED) implemented since 1982. It was developed for community hospitals in according to the use of selected essential drug for medical services in order to save costs and promote rational drug use. The implementation of the list is limited only to the public sector. The current requirements regarding the use of NLED are outlined in the Office of Prime Minister's Rules on Government

Procurement which mandates public health facilities to use no less than 60 percent of their drug budget (80 percent for facilities under the Ministry of Public Health) to buy drugs listed in the NLED, and prices of the drugs purchased must not exceed the medium price (Pharmaceutical Administration Reform, 2005).

One or both of the first two lists are used, the third list may not be necessary. Nevertheless, a negative list can also be developed and used along with the positive lists. In this case, the negative list can contain categories of drug seen as unnecessary and will not be considered for listing in any positive lists. Drug list development and revision is a repetitive process. A formal system should be instituted to carry out this task. Selection of drugs to be included in each of the drug lists can be implemented by an expert committee. The process for making selection decisions should be transparent, and rely on a set of criteria that are rational. Pharmacoeconomic tools can be employed to aid the decision for enlisting cost-effective medicines for reimbursement. In some countries, Australia and Canada, for example, pharmaceutical manufacturers are required to include a pharmaceutical expenditure analysis in each new submission for inclusion on the reimbursement list.

The procurement process is an important step in drug management system. An effective procurement process ensures the availability of the right drugs in the right quantities, at reasonable prices, and at recognizable standards of quality. The evidence from these worldwide experiences suggests that a set of common factors must be addressed before establishing regional collaboration for the procurement of drugs (WHO, 2009). In 1981, Fiji Pharmaceutical and Biomedical Department established the Bulk Purchasing Scheme to serve island states. This study used a pricing survey revealed Fiji Pharmaceutical Scheme (FPS) prices. The results found that the Bulk Purchasing Scheme is not yet functioning envisioned, and the FPS has a pure "client" relationship with small island states. The challenges include improving communication among countries, reducing delivery time, and developing a procurement plan for Bulk Purchasing Scheme in island states by using modern warehouse and applying advanced management tool (WHO, 2009).

The drug storage and distribution system in the hospitals are required to supply the medication prescribed for each inpatient. The drug distribution system includes all the processes that occur between the prescription of a drug and the

administration of that drug to patient. There are many varieties of drug distribution system in use throughout the world, but all have the same goal: to ensure that each dose of medication administered to each patient is exactly that which was intended by the prescriber. A measure of the quality of any drug distribution system is the incidence of medication errors, where a medication error is any discrepancy between the medication prescribed and that administered. In developed countries such as Germany, unit dose system begun to implement since 1993 (Schommer et al, 1993) Reasons for the move to unit dose drug distribution include shortages of nursing staff and desire to reduce risk, reduce costs and increase pharmacists' involvement with drug therapy (Negele, 1994). However, although the unit dose system was shown to decrease medication errors in the USA in the 1960s, it cannot be assumed that this will also apply to other health care cultures in the 1990s. It is not known how the medication error rates of the traditional and unit dose systems in Germany compare with each other or with other drug distribution systems such as the ward pharmacy system.

And finally, the irrational use of medicines is a major problem world-wide. For example, in 2003 only about 60% of countries had clinical guidelines updated in the previous five years; just over 70% had a national essential medicines list but only 30% used this list for insurance reimbursement. A major reason for this lack of implementation is that promoting rational use of medicines has received little political attention. It has not been institutionalized within health systems in many countries and is therefore lacking a national structure for developing, coordinating and monitoring policy. Many rich nations have adapted their health systems to address this issue by setting up national systems for medicines selection, prescription monitoring, obligatory continuing medical education, etc. Unfortunately, few low- and middle-income countries have done this (WHO, 2009).

In Thailand, many studies had been performed on drug management in hospitals. Aunsanun (1999) evaluated the impact of DMS reform in hospitals affiliated with MOPH. The results showed that most of the head of pharmacy department strongly agree with drug selection, monitoring and drug use evaluation criterion to serve for saving of drug budget. However, they were not certain that the measures would accomplish its purpose.

In 2006, Sripairoj investigated the performance indicators of the provincial PTC for drug management. This study found that the PTC at all levels of hospitals had the same activity; that was the selection of drugs into or out of hospital drug lists. There were few PTC meetings in the hospital because the PTC chairpersons in regional or provincial hospitals wanted to delay the selection of new drugs or expensive drugs into hospital drug lists. The problem of improving a PTC performance in district hospitals was due mainly to the fact that doctors usually worked in the hospitals for only a few years. PTC performance indicators for drug management should be set up to reflect goals, objectives, and functions at each hospital level and should include, for example, the number of PTC meetings and the number of drug items in hospital drug lists based on the criteria of the Ministry of Public Health. (Sripairoj, 2006)

Watchainan (2005) studied drug administration system and steps of the drug management in Khon Kaen hospital. The results of study found that the quality indexes of the drug administration system such as drug quality certificate, drug procurement, drug inventory, drug over stock, drug dead stock, drug expired, and drug report effected to the drug administration for benefits in the hospital.

Supasirivittaya (2006) evaluated drug inventory management in hospitals located in the central region of Thailand under the Office of Permanent Secretary for Public Health according to DMS reform. The results of this study indicated that all hospitals could imply almost all criterions of drug management system reform. The problems were found to be: the provincial drug management was not timely, most hospitals faced of lack stock, procurement was not in accordance with the procurement plan, and higher drug price was found. More problems also resulted from provincial co-procurement of drugs. The suggestions for problem-solving were stock-controlling, updating procurement plan, establishing appropriate drug selection criteria, and setting up of reporting system to the provincial drug management committee. Obvious policy for appropriate drug selection and rational drug use in each hospital was also suggested.

A descriptive research was performed at Khon Kaen Health Promotion Centre (HPC) for drug management investigation. The data were analyzed by ABC analysis. The results found that three groups of drugs (31 drug items) had very high values;

namely vaccines, osteoporosis drugs, and hormones. Suggestion included that the HPC should develop the data collection system of drug inventory for trends and direction analysis to increase efficiency of the drug management, and to reduce problems of drug over stock and expired drug for economy and efficiency of government budget. (Tongpue, 2007)